JAN 2 3 2001

K003628

10 Appendix: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information.

Establishment:

Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, N.J. 08830

Registration Number: 2240869

Contact Person: Mr. Jamie Yieh
Technical Specialist, Regulatory Submissions
(732) 321-4625
(732) 321-4841

Date of Summary Preparation: November 22, 2000

Device Name:

- Trade Name: MAGNETOM Rhapsody System

- Classification Name:
  Magnetic Resonance Diagnostic Device, CFR § 892.1000

- Classification: Class II

- Performance Standards:
  None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

• Device Description:

• Intended Use

The MAGNETOM Rhapsody system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Rhapsody system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculoskeletal, vascular, cardiac, and neuro systems. The images produced by the Rhapsody system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Rhapsody may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

• Technological Characteristics

The MAGNETOM Rhapsody System is a 1.0 T open superconducting magnet designed scanner. It consists of the same types of hardware (with a modified gradient coil, RF body resonator, and magnet) that are currently existing with Harmony and Open Viva systems. The software is the same as what is currently available with Harmony system.

• General Safety and Effectiveness Concerns:

Operation of the MAGNETOM Rhapsody System is substantially equivalent to the commercially available MAGNETOM 1 T Harmony System and 0.2 T Open Viva System. The following are the safety parameter with action levels:

- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

and performance levels

- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

specified by the FDA guidance document for MR Diagnostic Devices that will be evaluated. The MAGNETOM Rhapsody will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM Harmony system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2001

Jamie Yieh
Technical Specialist, Regulatory Submissions
Siemens Medical Systems, Inc.
Sales and Service
186 Wood Avenue South
ISELIN NJ 08830

Re: K003628
Magnetom Rhapsody System
Dated: November 22, 2000
Received: November 24, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Yieh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K00 3628

3 Appendix: Indications for Use Statement

In accordance with FDA requirements (as of 1/1/96), the indications for use statement is attached on a separate page.

510(k) Number (if known) K00 3628

Device Name: MAGNETOM Rhapsody System

Indications for Use:

The MAGNETOM Rhapsody system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The MAGNETOM Rhapsody system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculoskeletal, vascular, cardiac, and neuro systems. The images produced by the Rhapsody system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Rhapsody may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

David A. Hagman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003628